

REMARKS

Reconsideration of the present application, as amended and in view of the following remarks, is respectfully requested. The application, as amended, includes claims 1, 2, 9-13, 30, 32, 33, 36-38, 42-47, 55-63 and 66-67, pending and under consideration. At the time the outstanding Office Action was mailed on March 17, 2006, claims 3-8, 14, 34, 35, 39-41, 48-54, 64 and 65 had been withdrawn from consideration, claims 43, 66 and 67 were allowed, claims 12, 46 and 47 were objected to only as depending upon rejected base claims, and claims 1, 2, 9-11, 13, 30, 32, 33, 36-38, 42, 44, 45 and 55-63 were rejected. For the reasons set forth below, Applicant submits that, and respectfully requests an indication that, each of pending claims 1, 2, 9-13, 30, 32, 33, 36-38, 42-47, 55-63 and 66-67 is in condition for allowance.

Applicant acknowledges and thanks the Examiner for the indication in the outstanding Office Action that claims 43, 66 and 67 are allowed and that claims 12, 46 and 47 are objected to as depending upon rejected base claims, but would be allowable over the prior art if rewritten in independent form. Applicant also acknowledges and thanks the Examiner for the indications in the outstanding Action that: (1) the objection to the specification has been withdrawn, (2) the rejection of certain claims as being anticipated by Grosse et al (WO 97/23174) has been overcome, and (3) the rejection of certain claims as being anticipated by Brosnahan, III (5,645,598) has been overcome. The remarks below address the only remaining issue in the present case.

Remarks Regarding Rejection of Claims Under 35 U.S.C. §103(a)

The only issue that remains in the present case is a rejection of claims 1-2, 9-11, 13, 30, 32, 33, 36-38, 42, 44, 45 and 55-63 under 35 U.S.C. 103(a) as being unpatentable over Ulrich (DE 19630256) in view of Michelson (6,123,705). Applicant traverses this rejection on the grounds that the Action fails to establish a *prima facie* case that the invention recited in the pending claims is obvious over the cited combination. Applicant also reserves the right to establish that the primary reference relied upon by the Examiner (the Ulrich reference) is antedated by the present inventor's prior invention. In view of the reasons for allowance set forth herein, however, antedating the Ulrich reference is unnecessary. The presently claimed invention is patentable over the cited combination even assuming *arguendo* that the reliance on the Ulrich reference is proper.

In traversal of this rejection, Applicant submits that the rejection was made based upon a misunderstanding of the Ulrich disclosure, and an erroneous assumption regarding the device disclosed therein. In making the rejection, the Examiner asserts that, "Ulrich teaches a first cylindrical fusion device being dumbbell shaped including a [sic] opposing end pieces." (Office Action, p. 3). In traversal, Applicant submits that Ulrich indeed does not disclose a fusion device that is dumbbell shaped. Indeed, to better understand the Ulrich disclosure, Applicant has obtained an English translation thereof, which is submitted herewith attached to the enclosed Information Disclosure Statement.

Upon careful consideration of the English translation of the Ulrich reference, together with the Figures included therein, a person of ordinary skill in the art at the time of

the present invention would have understood that the component referenced in the Action is actually NOT “dumbbell shaped.” Instead, the identified component is described in the Ulrich reference as a “pin” 3 that is “formed as a predominantly hollow body,” and includes a “disk” 18 at one end, a “ring” 17 at the opposite end and two opposing and spaced apart “crosslinks” 19 join the ring to the disk. The orientation of these elements is most clearly seen in Fig. 5 of Ulrich, which is a cross section taken along the vertical section line shown in Fig. 4. With reference to Fig. 5 crosslinks 19 are clearly shown to be positioned at opposing edges of disk 18, and operate to attach ring 17 to disk 18 at opposing and distant positions. This orientation is also apparent from consideration of Fig. 2 and Fig. 6, each of which depicts a cross section view along the horizontal section line shown in Fig. 4. In Fig. 2 and Fig. 6, only one crosslink 19 is shown, and it is not hatched because it is not sectioned in this view. Indeed, the only sectioned portions of pin 3 that are shown in this view are sections of disk 18 and two opposite portions of ring 17.

With reference again to Fig. 4 of the Ulrich reference, a portion of disk 18 is visible in this view *through* ring 18, but crosslinks 19 are not visible in this view because they are hidden *behind* ring 17. Indeed, as stated in the English translation of Ulrich submitted herewith, “So that the [insertion] instrument can be introduced ... through the hollow middle of the pin 3 into the recess [21 in disk 18], the crosslinks 19 must run at a sufficient distance from the pin axis.” Because pin 3 of the device disclosed in the Ulrich reference includes a ring at one end and includes opposing crosslinks attached to the ring

17 and disk 18, Applicant submits that this reference cannot be relied upon as disclosing a fusion device that is dumbbell shaped, as asserted in the outstanding Office Action.

Moreover, a person of ordinary skill in the art would readily understand upon careful consideration of the Ulrich reference that modification of the device in the manner proposed in the outstanding Office Action would render it unsatisfactory for its intended purpose. The outstanding Action asserts that, “Ulrich fails to teach nesting a second dumbbell fusion device with the first. Michelson also teaches cylindrical fusion devices which are nested together by utilizing a cutout region...It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Michelson of nesting two fusion device [sic] together with the fusion devices of Ulrich...” (Office Action, pp. 3-4). This assertion is flawed, however, when the disclosure of Ulrich is taken for what it actually teaches. As seen most clearly in Fig. 6 of the Ulrich reference, crosslinks 19 are positioned laterally when the device is implanted in the vertebral gap 2” between vertebral bodies 2. Modification of pin 3 by forming a cutout region in a lateral portion of pin 3, as would be necessary to achieve the combination asserted in the outstanding Office Action, would render pin 3 unsatisfactory for its intended purpose. Specifically, this modification would result in the removal of one of the two crosslinks 19, and removal of an arc from ring 17, either one of which would have the effect of rendering pin 3 unstable and unable to achieve its intended purpose, i.e., support of a spinal load.

Section 2143 of the Manual of Patent Examining Procedure (“MPEP”) sets forth three well-established criteria that must be met for an Examiner to establish a *prima facie*

case of obviousness, one of which is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Another well-established rule is stated in MPEP §2143.01 as follows: "If [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." (case citation omitted). Because the modification proposed in the outstanding Action would render the Ulrich device unsatisfactory for its intended purpose, Applicant submits that there can be no suggestion or motivation to make the proposed modification, and the Action necessarily fails to establish a *prima facie* case of obviousness of claims 1-2, 9-11, 13, 30, 32, 33, 36-38, 42, 44, 45 and 55-63. As a result, the rejection of these claims asserted in the outstanding Action is overcome, and Applicant submits that these claims are allowable over the references of record.



Closing

Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, as amended and including claims 1, 2, 9-13, 30, 32, 33, 36-38, 42-47, 55-63 and 66-67 pending and under consideration, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

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RESPONSE TO OFFICE ACTION

Serial No. 10/634,711

Attorney Docket No. MSDI-465/PC329.14

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